

REMARKS

The Office Action mailed February 26, 2003, has been received and reviewed. The Office Action states that claims 1 through 8 are pending. Applicants note that as of the Election of Species and Preliminary Amendment filed December 2, 2002, only claims 1 through 7 were present in the application. All claims stand rejected. Applicants have amended claims 1, 3, 4, and 7 and added new claims 8 and 9 herein. Applicants respectfully request reconsideration of the application as amended herein. All amendments are made without prejudice or disclaimer.

Formal Matters

Applicants gratefully note the withdrawal of the election of species requirement and believe no further action is required on this point.

35 U.S.C. § 112 ¶ 1 Rejection

Claims 1 through 7 were rejected as assertedly lacking a sufficient written description in the specification and, thus, lacking enablement. The Office Action acknowledges the specification is enabling for: "A recombinant adenovirus based nucleic acid molecule comprising at least one functional inverted terminal repeat, and wherein the precursor recombinant nucleic acid molecule comprises at the 3' terminus a recombinantly fused sequence complementary to an upstream part of the same strand of the precursor recombinant nucleic acid molecule." (Office Action at page 3).

In order to expedite prosecution, the claims have been amended. As amended, claim 1 now reads:

1. A recombinant nucleic acid molecule produced by the action of a nucleic acid polymerase in a complementing cell comprising at least the E1A gene of an adenovirus on a precursor molecule; wherein
said precursor recombinant nucleic acid molecule is a recombinant nucleic acid molecule based on or derived from an adenovirus,
said precursor molecule has at least one functional inverted terminal repeat,
said precursor molecule comprises all other adenovirus derived genetic information not present in said complementing cell and necessary for replication, and
said precursor molecule is in a linear and essentially single stranded form and

comprises, at the precursor molecule's 3' terminus, a recombinantly fused sequence complementary to an upstream part of the same strand of the precursor molecule, to allow said sequence and said upstream part to form base pairs and function as a start-site for said nucleic acid polymerase.

Applicants thus respectfully submit that as amended, claim 1 is enabled by the specification. Applicants respectfully request that amended claim 1, with claims 2-9 dependent therefrom, be allowed.

35 U.S.C. § 112 ¶ 2 Rejection

Claims 1 through 7 were rejected as assertedly being indefinite. The language "a recombinant nucleic acid molecule derived from" in claim 1 was objected to as allegedly indistinct. By this amendment, Applicants have removed this language from claim 1. Applicants respectfully submit that amended claim 1 is definite, as are the claims dependent therefrom. Accordingly, it is requested this rejection be withdrawn and the claims allowed.

35 U.S.C. §§ 102(e) and 103(a) Rejections

Rejections over U.S. Patent 6,040,174 to Imler

Claims 1-2, 5-7 were rejected in the Office Action as assertedly being anticipated under 35 U.S.C. § 102(e) by U.S. Patent 6,040,174 to Imler. In the alternative, these claims were rejected as assertedly obvious under 35 U.S.C. § 103(a) over the same reference. Applicants respectfully traverse these rejections and submit they should be withdrawn and the amended claims allowed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Similarly, the standard for a § 103(a) rejection is set forth at M.P.E.P. 706.02(j), which states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The recombinant nucleic acid molecule of claim 1 is derived from a precursor recombinant nucleic acid molecule based on or derived from an adenovirus. The precursor molecule includes a recombinantly fused sequence complementary to an upstream part of the same strand of the precursor molecule to allow said sequence and said upstream part to form base pairs and function as a start sight for nucleic acid polymerases, thereby generating the recombinant nucleic acid molecule, recited in claim 1 (see Fig. 13 of the specification for a cartoon of the concept). Therefore, **the recombinant nucleic acid molecule of claim 1 comprises this recombinantly fused sequence.** This element is not taught or disclosed by Imler *et al.* Therefore Applicants respectfully submit that claim 1 defines over Imler *et al.*, as do the claims dependent therefrom. Accordingly, Applicants request these rejections be withdrawn and the claims allowed.

Rejections over U.S. Patent 5,994,106 to Kovesdi et al.

Claims 1-2, 5-7 were rejected in the Office Action as assertedly being anticipated under 35 U.S.C. § 102(e) by U.S. Patent 5,994,106 to Kovesdi *et al.* In the alternative, these claims were rejected as assertedly obvious under 35 U.S.C. § 103(a) over the same reference. Applicants respectfully traverse these rejections and submit that the amended claims should be allowed.

As discussed previously herein, the recombinant DNA molecule of claim 1 is derived from a precursor recombinant nucleic acid molecule based on or derived from an adenovirus, which includes a recombinantly fused sequence complementary to an upstream part of the same strand of the precursor molecule to allow said sequence and said upstream part to form base pairs and function as a start sight for nucleic acid polymerases, thereby generating the recombinant nucleic acid molecule of claim 1. The recombinant nucleic acid molecule of claim 1 thus comprises this recombinantly fused sequence. This element is not taught or disclosed in Kovesdi *et al.* Applicants thus respectfully submit that claim 1 defines over Kovesdi *et al.* as do the claims dependent therefrom. Accordingly, Applicants request that these rejections be withdrawn and the claims allowed.

Rejections over U.S. Patent 5,652,224 to Wilson et al.

Claims 1-7 were rejected in the Office Action as assertedly being anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,652,224 to Wilson *et al.* In the alternative, these claims were rejected as assertedly obvious under 35 U.S.C. § 103(a) over the same reference. Applicants respectfully traverse these rejections and submit that the amended claims should be allowed.

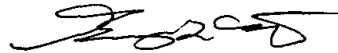
As discussed previously herein, the recombinant DNA molecule of claim 1 is derived from a precursor recombinant nucleic acid molecule based on or derived from an adenovirus, which includes a recombinantly fused sequence complementary to an upstream part of the same strand of the precursor molecule to allow said sequence and said upstream part to form base pairs and function as a start sight for nucleic acid polymerases, thereby generating the recombinant nucleic acid molecule of claim 1. The recombinant nucleic acid molecule of claim 1 thus comprises this recombinantly fused sequence. This element is not taught or disclosed in Wilson *et al.* Applicants thus respectfully submit that claim 1 defines over Wilson *et al.* as do the claims dependent therefrom. Applicants respectfully request these rejections be withdrawn and the claims allowed.

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CONCLUSION

Claims 1-9 are believed to be in condition for allowance and early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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